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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,034	11/24/2003	T. Douglas Mast	END-5042USCIP	4797

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EXAMINER	
JAWORSKI, FRANCIS J	
ART UNIT	PAPER NUMBER
3768	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,034	MAST, T. DOUGLAS	
	Examiner	Art Unit	
	Jaworski Francis J.	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/5/06, 8/29/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/29/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1 –4, 9- 10, 16 – 19, 23 – 24, 30 are rejected under 35 U.S.C. 103(a) as being obvious over Okazaki (US5005580), or in the alternative as obvious based upon Okazaki in view of Dory (US5354258, of record), in either case further in view of any one of Watkins et al (US5769790) or Acker et al (US6508774).

Okazaki as noted in the Office action mailed teaches receiving ultrasound imaging signals (which are time varying signals insofar as they carry information and are derived from the RF carrier frequency of the ultrasound) during first and second time periods into 20a with processing and subtraction therebetween in 20b such that a subtraction image 26 of Fig. 6 is formed which image tracks discrete increments of medical therapy by kidney stone or calculus destruction including through the completion of the treatment, see col. 5 line 46 – col. 6 line 2. The context indicates that the method is practiced all the way from a baseline image of a treated region in its anatomic surroundment prior to treatment through just sufficient completion of treatment as determined from the succession of differential images. In the alternative, Dory makes clear that subtraction images may be iteratively obtained on a very short time base soas to be time-varying in order to monitor the course of treatment particularly when the treatment is causing rapid irreversible changes to the body.

Whereas these references do not discuss and therefore do not take into account the amplitude and phase differences between the first and second signals, it would have been obvious in view of Watkins et al col. 3 line 59 – col. 4 line 33 that when a tomography or a B-mode image for the subtraction pair is obtained such as called for in the former, a phased array

might conventionally be used and so one must take into account the amplitude and phase of each signal in all received scanlines in order to beamform and composite the image. Similarly in the case of Acker et al, when one uses an array commonly to treat and to image the progress of treatment e.g. by amplitude changes attendant to cavitation, one must also track the phase in order to spatially direct the imaging mode beam, see col. 8 line 13 – col. 9 line 18 and col. 11 lines 29 – 51. Finally, in the case of Freundlich et al .(Claims 1 –4, 9 – 10, 16 – 19, 23 – 24 as amended)

Such paired images are subtracted in an iteration which incrementally tracks treatment during its course. (claim 30 as amended).

Claims 1 – 4, 9 – 10, 16 – 19, 23 – 24, 30 are rejected under 35 U.S.C. 103(a) as being obnvious over Lizzi et al (US6533726) in view of Dory (US5354258, of record), further in view of Watkins et al or Acker et al as the latter were applied above. . Lizzi et al in and of itself teaches receiving (time-varying as explained above) ultrasound imaging signals (Fig. 3 elements 310, 320, 330) during first and second and third time periods, and processing and subtracting the signals (340, 345) and generating an indication therefrom about the effect of the medical diathermy treatment in causing transitory or permanent tissue changes within the anatomic surroundment up to and including treatment termination and subsequent to an initial baseline reading. Although Lizzi et al do not explicitly state, it would have been obvious in view of Dory that such images may be spatial B-mode scans, and in view of the further teachings that a phased array type approach may be used in which both amplitude and phase are taken into account in the processof forming the final output image.(Claim 1 – 4, 9 – 10, 16 – 19, 23 – 24 as amended).

Again, such paired images are subtracted in an iteration which incrementally tracks treatment during its course. (Claim 30 as amended).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al as applied to claim1 above, further in view of Dory and Watkins et al/Acker et al, and further in view of Cain et al (US5590657). With respect to Cain, whereas the former are silent as to motion compensation, it would have been obvious in view of the latter cols. 5-6 to compensate for phase aberration effects by a phase compensation function in order to re-focus the ultrasound imaging or treatment on the desired target volume in the event of movement within the target area. (Claim 5 as amended).

Claims 6-7, 11- 12, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al as applied to claim 1 above, further in view of Dory (US5354258) and Watkins et al/Acker et al. Whereas the former are silent as to output scaling, it would have been obvious in view of Dory to perform scaling by element 74 on the ultrasound difference image signal (output of 7) in relation to the initial image signal S2 , sSince Dory is also tracking the differential tissue image as representing the progress of the treatment and scaling allows blending with the very initial anatomic or B-mode image as a second image type so that the absolute progress of the therapy can be tracked. Otherwise the arguments above regrrding Watkins et al/Acker et al apply.(Claims 6, 11 - 12, 20 as amended).

The use of power scaling would have been obvious since Lizzi et al is concerned with attenuation changes in the tissue which is a power measurement (see col. 5 top) ; also Dory col. 5 lines 55-68 is concerned with power absorption by tissues.(Claims 7, 21 as amended).

Claims 8, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al, in view of Dory and Watkins et al/Acker et al, as applied to claim 1 above, and further in view of Geiser et al (US6106470). The former are silent as to spatial filtering. However it would have been obvious in view of the latter to provide at least some spatial filtering in post-processing an image in general for display in order to reduce graininess by using local average values. (Claim 8).

Claims 13- 15 and 25 – 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al, or further in view of Dory as applied to claim 1 above, and further in view of both Dory as applied with respect to scaling of the difference signal (claim 6 supra) and also Geiser et al as applied with respect to spatial filtering (Claim 8) above, which evidence that both of these features were known in association with ultrasound monitoring of medical treatment of in association with general anatomic ultrasound imaging. The latter references are applied as above. (Claims 13, 25, 28 – 29 as amended).

In both of the base reverences both a first and second image may be received after the initial treatment as the image differencing system iteratively advances during treatment increments, in essence a repeating of the claim 2 argument supra.. (Claims 14, 26 as amended).

The base argument against claim 3 that the iteration of differencing proceeds up to the final treatment as a viewing tool of its completion applies here (Claims 15, 27 as amended).

Claims 31- 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okazaki or Lizzi et al, or further in view of Dory and Watkins et al/Acker et al as applied to claim 30 above, and further in view of Fujimoto et al (US6540700). Whereas the former are silent as to the issue of signal averaging, it would have been obvious in view of the latter to use signal averages, see

col. 18 line 60 – col. 19 line 4 as well as col. 20 lines 12 – 23 since this permits small variations in signal levels due to noise to average out such that a small-difference circumstance as is measured during tissue treatment may be more accurately represented. (Claim 31 as amended).

Such averaging would be understood to be a cumulative summation and scaling because one cannot multiply the resulting brightness gradation of the video display. (Claim 32 as amended).

Response to Arguments

Amendatory language directed to accounting for phase and amplitude information in the formation of treatment tracking differential ultrasound images is not considered to create patentable subject matter since in the case of well-known phased array imaging whether practiced apart from or in association with the treatment sensors the phase of the received signal must be taken into account in spatially assembling the image data into component frames for the differencing.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

09-02-06

Francis J. Jaworski
Primary Examiner